UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

BARBARA HEINRICH and GREGORY HEINRICH,

Plaintiffs

v.

ETHICON, INC.; ETHICON LLC; and JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

Order Granting in Part Defendants' Motion in Limine No. 9

[ECF No. 137]

This case is one of many thousands of cases that were joined in multidistrict litigation (MDL) in the United States District Court for the Southern District of West Virginia. The case was transferred to this court for trial in January 2020. ECF No. 69.

The defendants filed a motion *in limine* seeking to exclude from trial medical device reports (MDRs) or "other anecdotal case reports discussing other patients' experiences with TVT-Secur or other pelvic mesh devices." ECF No. 137 at 1. MDRs are adverse event reports sent to the Food and Drug Administration (FDA) by hospitals, physicians, or manufacturers when they have notice that a device "may have caused or contributed to a death or serious injury." 21 U.S.C. § 360i(a)(1)(A); *see also id.* § 360i(b)(1).

A. Excluded by Statute

The defendants argue that reports by hospitals and physicians are not admissible as a matter of federal statute under 21 U.S.C. § 360i(b)(3). The defendants also contend that their own reports as manufacturers are based on hospital and physician reports, so those also should be excluded under § 360i(b)(3). The plaintiffs do not specifically respond to this argument.

Section 360i(a)(1)(A) directs the Secretary of Health and Human Services to issue regulations that require device manufacturers "to report to the Secretary whenever the manufacturer . . . receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices . . . may have caused or contributed to a death or serious injury." Similarly, section 360i(b)(1) requires device user facilities to report to the Secretary and to the manufacturer whenever they become "aware of information that reasonably suggests" that a device has or may have caused serious injury or death. A device user facility means "a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office." 21 U.S.C. § 360i(b)(6)(A).

Under section 360i(b)(3), "[n]o report made . . . by . . . a device user facility" or an employee thereof, or "a physician who is not required to make such a report, shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual or physician who made the report had knowledge of the falsity of the information contained in the report." There is no similar provision for reports made by manufacturers.

The plaintiffs have not responded to the defendants' argument that any MDR reports made by device user facilities are statutorily excluded from evidence. I therefore grant this portion of the defendants' motion as unopposed. LR 7-2(d).

But there is no statutory basis to exclude the defendants' own MDRs, even if their reports were founded on reports made to them by device user facilities. If Congress wanted to exclude manufacturers' reports from evidence, it could have said so, but it did not. *See In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.*, 505 F. Supp. 3d 770, 780 (S.D. Ohio 2020) ("Manufacturer reports are not addressed by § 360i(b), but § 360i(a). Accordingly, manufacturer MDRs are admissible insofar as § 360i(b)(3) does not apply to

them."); *Chism v. Ethicon Endo-Surgery, Inc.*, No. 4:08CV00341-WRW, 2009 WL 3066679, at *1 (E.D. Ark. Sept. 23, 2009) ("Although device user facilities report to manufacturers, who then base their reports to the FDA on the user reports, § 360i does not prohibit the admissibility of manufacturer reports into evidence, or other uses of the reports in civil actions."). I therefore deny the defendants' motion to exclude their own MDRs on this basis.

B. Unreliable Hearsay

The defendants argue that MDR and other voluntary reports are unreliable because they are anecdotal, and Ethicon can report only what it is told by physicians and hospitals. The plaintiffs respond that I should deny the motion without prejudice because the defendants have not identified which MDR reports they seek to exclude and the admissibility of any particular MDR is dependent on the report's context and content. The plaintiffs argue that the reports are not hearsay because they are evidence of the defendants' notice of reports of adverse events associated with the TVT-Secur.

The defendants do not provide any reports they seek to exclude. Nor do they identify what evidence they are referring to when they mention other anecdotal case reports. The plaintiffs similarly do not provide any reports they may seek to use at trial, except the MDR for Barbara Heinrich, which would not have provided relevant notice to the defendants prior to her implantation. Neither side has presented me with the evidence at issue. The parties therefore have left me unable to rule except to state as a general matter that reports to the FDA are inadmissible hearsay unless the party offering the reports can demonstrate they fall within an exception to the hearsay rule or are being offered for a non-hearsay purpose. Fed. R. Evid. 801-07. To that extent, the defendants' motion *in limine* is granted as to their own MDRs and other anecdotal reports.

C. Conclusion

I THEREFORE ORDER that the defendants' motion *in limine* No. 9 **(ECF No. 137) is GRANTED in part** as explained above.

DATED this 1st day of November, 2021.

ANDREW P. GORDON
UNITED STATES DISTRICT JUDGE